

Amendment No. 2 to SB0753

Roberts
Signature of Sponsor

AMEND Senate Bill No. 753*

House Bill No. 1317

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, Part 3, is amended by deleting the part and substituting the following:

63-10-301. Designation.

(a) There is created a board of pharmacy, referred to herein as the "board," to be administratively attached to and receive administrative support from the division of health related boards within the department of health.

(b) The responsibility for enforcement of the provisions of parts 2-7 of this chapter and all laws that pertain to the practice of pharmacy is vested in the board.

(c) The board has all of the duties, powers, responsibilities, and authority necessary for the enforcement of parts 2-7 of this chapter, as well as other duties, powers, and authority as it may be granted.

(d) The board shall cooperate with state and federal agencies regarding any violations of a pharmacy drug or drug-related law.

(e) If a state of emergency is declared that involves the board under this part, then the board may waive the requirements of this chapter to protect the public health, safety, or welfare of its citizens and to facilitate the provision of drugs, devices, and pharmacist care services to the public.

63-10-302. Membership.

The board consists of nine (9) members to be appointed by the governor as follows:

- (1) One (1) consumer member;
- (2) One (1) registered pharmacy technician; and
- (3) Seven (7) pharmacists who possess the qualifications specified in § 63-10-303.

63-10-303. Qualifications.

- (a) Each pharmacist member of the board must, at the time of their appointment:
 - (1) Have been a resident of this state for no less than five (5) years;
 - (2) Must be a graduate of a recognized school or college of pharmacy;
 - (3) Be licensed and in good standing to engage in the practice of pharmacy in this state;
 - (4) Be actively engaged in the practice of pharmacy, as defined in § 63-10-204, in this state; and
 - (5) Have at least five (5) consecutive years of experience in the practice of pharmacy providing patient care services after licensure.
- (b) Each registered pharmacy technician member of the board must, at the time of their appointment:
 - (1) Have been a resident of this state for not less than five (5) years;
 - (2) Be currently licensed and in good standing as a registered pharmacy technician in this state;
 - (3) Be actively practicing as a registered pharmacy technician in this state;
 - (4) Be a certified pharmacy technician as defined by board rules; and
 - (5) Have at least five (5) consecutive years of experience as a pharmacy technician after registration.
- (c)
 - (1) Each consumer member of the board must, at the time of their appointment:

(A) Be a current resident of this state for at least five (5) years;

and

(B) Not be a licensed healthcare professional.

(2) The consumer member must not own or have a financial or other interest in any healthcare facility or healthcare business during the consumer's term on the board.

63-10-304. Appointment.

(a) Interested pharmacist groups, including, but not limited to, the Tennessee Pharmacists Association, may annually recommend five (5) duly qualified persons for each vacancy from whom the governor may be requested to make appointments. The governor shall consult with such groups to determine qualified persons to fill the positions. This subsection (a) does not apply to the consumer member serving on the board.

(b) A member appointed to the board shall take oath or affirmation that the member will faithfully and impartially perform their duties within ten (10) days after the member's appointment to the board. A member's oath or affirmation taken pursuant to this subsection (b) must be filed with the secretary of state.

(c) In making appointments to the board, the governor shall strive to ensure that at least one (1) person serving on the board is sixty (60) years of age or older, one (1) person serving on the board is a member of a racial minority, and the members on the board are representative of a variety of practice settings.

63-10-305. Terms of office and removal.

(a) Board members shall serve seven-year terms or until their successors have been qualified. A member of the board is not eligible for reappointment; provided, however, that a member may be reappointed for one (1) full term if the member is appointed to fill a vacancy for which occurred prior to the expiration of a former member's term.

(b) The terms of the members of the board are staggered so that the terms of no more than three (3) members expire in one (1) year.

(c) A member of the board who is found to have committed misconduct may be removed by the governor upon the recommendation of the remaining members. As used in this subsection (c), "misconduct" means:

(1) The refusal or inability of a board member to perform their duties as a member of the board due to efficiency, irresponsibility, and unprofessional manner;

(2) The misuse of office by a member of the board to obtain personal, pecuniary, or material gain or advantage for their self or another through the office; or

(3) The violation of a law pertaining to the practice of pharmacy or the distribution of drugs and devices.

63-10-306. Organization.

(a) The pharmacist members of the board shall annually appoint a president and a vice president.

(b) The president of the board, and the vice president in the president's absence, shall preside at all meetings of the board and is responsible for the performance of all duties and functions of the board under this part.

(c) The board president may, if deemed necessary, split the board into panels of three (3) or more to conduct contested case hearings regarding disciplinary matters. A quorum of at least (3) panel members is required at such hearings.

(d) The board shall meet at least annually and at such other times as it deems necessary to perform its duties under this chapter. A majority of the members of the board constitutes a quorum for the conduct of board meetings and, except where a different number is required by this part or by any board rule, all actions of the board must be by a majority of a quorum.

(e) The members of the board receive a per diem of one hundred dollars (\$100) for each day the member is engaged in performance of the official duties of the board, and must be reimbursed for all reasonable and necessary expenses incurred in connection with the discharge of such official duties. All reimbursement for travel expenses are in accordance with the comprehensive travel regulations as promulgated by the department of finance and administration and approved by the attorney general and reporter.

63-10-307. Executive Director.

(a) The board shall consult with the division of health related boards in the department of health in appointing a person to serve as executive director of the board; however, the board is not bound by any recommendation of the division. The executive director must be licensed as a pharmacist in this state for at least five (5) consecutive years immediately preceding the appointment.

(b) The board shall specify the executive director's duties, and the executive director is responsible for the performance of the administrative functions of the board, which may include, but are not limited to:

- (1) Recording and compiling the minutes of the board;
- (2) Supervising employees assigned by the division of health related boards to support the board;
- (3) Performing studies and research as the board or division directs;
- (4) Representing the board at functions as authorized by the board and the division; and
- (5) Serving as a consultant to the division in its enforcement duties on behalf of the board.

(c) The board may dismiss the executive director without consulting with the division.

63-10-308. Board employees.

The board may, at its discretion, employ persons it deems necessary to properly conduct board business and to allow the board to fulfill its responsibilities under this part.

63-10-309. Enforcement of pharmaceutical laws – Promulgation of rules.

(a) The board shall enforce laws in this state relating to the practice of pharmacy; the manufacture, distribution, and sale of drugs; the medication use process, including, but not limited to, compounding, selection, preparation, production, dispensing, and distribution; patient administration; and the education and monitoring of drugs, devices, chemicals, and poisons.

(b) The division of health related boards shall employ the necessary administrative and clerical staff and investigators who are pharmacists to carry out the board's duty to enforce pharmaceutical laws. The pharmacist investigators may conduct inspections of pharmacies and other site where drugs, medicines, chemicals, pharmaceuticals, or poisons are manufactured, stored, sold, dispensed, distributed, or administered and shall conduct investigations of a board licensee. The pharmacist investigators may also assist in inspections and investigations undertaken by other health related boards attached to the division, and investigators assigned to these other health related boards may assist pharmacist investigators as appropriate.

(c) The board shall promulgate rules:

(1) To establish minimum standards and conditions for the operation of a pharmacy;

(2) Regarding the practice of pharmacy in this state to protect the health and welfare of the citizens of this state;

(3) Regarding professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy;

(4) To set minimum standards and conditions for receiving, preparing, maintaining, transferring, and dispensing of prescription orders; and

(5) To ensure that persons who are blind, visually impaired, or otherwise print disabled have appropriate access to prescription labels, bag tags, and medical guides.

(d)

(1) The board shall:

(A) Keep a record of the board's meetings and other proceedings;

(B) Issue and maintain a register of all persons who have been issued licenses and who have had their licenses renewed; and

(C) Maintain a register of pharmacists who have been designated as a pharmacist-in-charge.

(2) The board may maintain a register of pharmacy technicians as necessary to maintain public welfare.

(e)

(1) The board may petition a circuit or chancery court having jurisdiction over persons who practice pharmacy in this state without a valid license or who have violated the provisions of parts 2-7 of this chapter or rules promulgated by the board to enjoin a person from continuing to practice in this state.

(2) The executive director may issue subpoenas for witnesses and records and to administer oaths to witnesses.

(f)

(1) Board members may join professional organizations and associations organized to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public.

(2) The board may authorize, subject to the approval of the commissioner, administrative and investigative personnel and board members to attend local, state, regional, and national meetings. All reimbursement for travel expenses directly incurred as a result of attending such meetings shall be in

accordance with the comprehensive travel regulations as promulgated by the department of finance and administration and approved by the attorney general and reporter.

(g) The board shall:

(1) Regularly notify licensed pharmacists of changes that are implemented or enforced by the board that affect the licensees resulting from newly promulgated rules, amended statutes, and adopted policies and guidelines;

(2) Establish and publish on its website the statutes, rules, policies, and guidelines that are implemented or enforced by the board and that affect licensees; and

(3) Require licensees to maintain a copy of the board of pharmacy statutes, rules, policies, and guidelines at the location in which they practice pharmacy.

(h) The board may issue advisory private letter rulings to any affected licensee making a request for a ruling regarding matters within the board's jurisdiction. The private letter ruling affects only the licensee making the inquiry and has no precedential value for any other inquiry or future contested case to come before the board. The board may resolve a dispute regarding a private letter ruling pursuant to declaratory orders under § 4-5-223.

63-10-310. Power of board to suspend, revoke, or refuse to issue licenses – Civil penalties.

The board may deny, restrict, or condition any application for licensure; revoke or suspend any license or certification previously issued; or discipline and assess civil penalties against an applicant, licensee, or holder of a certificate upon a finding that the applicant, licensee, or holder of a certificate has:

(1) Been convicted of a criminal offense, including, but not limited to, violating a law of this state or of the United States relating to drugs or to the practice of pharmacy;

(2) Been addicted to the use of alcohol, narcotics, or other drugs;

(3) Engaged in conduct that is prohibited or unlawful under parts 2-7 of this chapter, or another state or federal law relating to drugs or to the practice of pharmacy;

(4) Exhibited an incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, confidence, and safety to the public;

(5) Been guilty of dishonorable, immoral, unethical, or unprofessional conduct;

(6) Had the license to practice pharmacy suspended or revoked by another state for disciplinary reasons; or

(7) Failed to comply with a lawful order or duly promulgated rule of the board.

63-10-311. License requirements.

(a) Except as otherwise provided in parts 2-7 of this chapter, it is unlawful for a person to engage in the practice of pharmacy unless the person is licensed or otherwise authorized to practice under parts 2-7 of this chapter.

(b) The board may establish the experience and educational qualifications necessary for admission to the board's licensure or certification examinations.

(c) The board may use any national certification, licensure examination, or contract with a qualified examination agency to prepare and administer its licensure examination. The board shall promulgate rules to establish the minimum score necessary to pass a licensure or certification examination required by the board.

(d) To apply for a pharmacist license, a person must:

(1) Be at least twenty-one (21) years of age;

(2) Be a graduate of a school or college of pharmacy recognized by the board; and

(3) Submit an application for licensure on forms approved by the board in writing or by online application and pursuant to rules promulgated by the board.

(e) The board may grant licenses to reciprocal applicants from other states upon making a determination that the qualifications of pharmacists licensed in other states are equivalent to or greater than requirements for licensure in this state. The board may refuse to issue licenses to reciprocal applicants from other states on grounds as determined by the board's rule.

(f) The board may license and register pharmacists, pharmacies, wholesalers, distributors, pharmacy technicians, pharmacy interns, manufacturers, third-party logistics providers, and other persons as may be required under federal or state law. This subsection (f) does not include manufacturers' representatives unless otherwise required by federal or state law.

(g)

(1) The board may promulgate rules to:

(A) Establish the criteria, timing and procedure for the renewal of licenses;

(B) Establish the requirements for continuing education for persons the board licenses or to whom the board issues certificates. This authority includes, but is not limited to, the establishment of the number of continuing education hours required, approval of providers and course content, enforcement of continuing education requirements, and qualification for waiver of the requirements or extension of time in which to obtain the continuing education; and

(C) Designate which national or other qualified pharmacy technician certification agencies are recognized in this state for maintaining certification as a pharmacy technician.

(2) The board shall promulgate rules to define the scope of practice of pharmacy technicians and the qualifications necessary to practice as a pharmacy technician.

63-10-312. Inspection of sites — Physicians regulated by board of medical examiners.

(a) The board or its designated agents are authorized to regulate the practice of pharmacy and to inspect any site or professional pharmacy practice, other than storage sites utilized by manufacturer's representatives, where drugs, medicines, chemicals, pharmaceuticals, or poisons are manufactured, stored, sold, dispensed, distributed, or administered.

(b) The authority over drug dispensing in the office of a physician licensed to practice under chapter 6 of this title is vested in the board of medical examiners.

63-10-313. Administrative fees.

(a) The board may promulgate rules to establish licensure fees necessary to carry out parts 2-7 of this chapter.

(b) All monies received by the board must be deposited and dispensed pursuant to § 63-1-137.

63-10-314. Administrative procedure.

All matters and procedures regarding the hearing and judicial review of a contested case arising under parts 2-7 of this chapter are governed under the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

63-10-315. Promulgation of rules regarding oversight of facilities that manufacture, warehouse, and distribute medical devices.

(a) The board shall promulgate rules regarding the board's oversight of facilities that manufacture, warehouse, and distribute medical devices. The rules promulgated under this subsection (a) must include the formation of an advisory committee, in accordance with § 4-5-205, composed of medical device industry representatives and a representative of the department of economic and community development.

(b) The rules promulgated pursuant to this section must be reviewed by the advisory committee every three (3) years to review the advancements of new medical device technologies.

(c) The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

63-10-316. Promulgation of rules.

All rules to effectuate this part must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. The headings to sections in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 3. This act takes effect July 1, 2023, the public welfare requiring it.